

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Vignina 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,711	03/04/2002	Patricia Rockwell	11245/46212	5402
7	590 06/17/2003		·	
Kenyon & Kenyon			EXAMINER	
One Broadway New York, NY 10004			LI, BAO Q	
		•	ART UNIT	PAPER NUMBER
			1648 DATE MAILED: 06/17/2003	5

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/090,711	ROCKWELL ET AL.			
Office Action Summary	Examiner	Art Unit			
·	Bao Qun Li	1648			
The MAILING DATE f this communication app ars on the cover sheet with the correspondence address					
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status					
1) Responsive to communication(s) filed on 20	Responsive to communication(s) filed on 20 August 2002.				
2a) This action is FINAL . 2b)	This action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims					
4)⊠ Claim(s) <u>1-52</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) is/are rejected.					
7) Claim(s) is/are rejected.					
8)⊠ Claim(s) <u>1-52</u> are subject to restriction and/or election requirement.					
Application Papers					
9) The specification is objected to by the Examiner.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
11) The proposed drawing correction filed on	is: a)□ approved b)□ disa	approved by the Examiner.			
. If approved, corrected drawings are required in reply to this Office action.					
12)☐ The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Info	mmary (PTO-413) Paper No(s) ormal Patent Application (PTO-152)			
U.S. Patent and Trademark Office PTO-326 (Rev. 04-01) Office	Action Summary	Part of Paper No. 5			

Application/Control Number: 10/090,711

Art Unit: 1648

DETAILED ACTION

Claims 1-52 are pending.

Election/Restriction

Upon reconsidering the claimed inventions, restriction is required under 35 U.S.C. 121:

I. Claims 1-10, 16-18 and 21-23, drawn to a nucleic acid encoding an amino acid sequence comprising a variable region of monoclonal antibody and a method or using the same, classified in class 424, subclass 23.1.

Upon elect group I, applicants are required to further elect one of nucleic acid encoding one amino acid sequence of one monoclonal antibody variable region elected from group consisting of ATCC Accession No. 11534, 12152 and 12153 to be examined on the merits. This is not a species election because each monoclonal antibody has different variable region with different structure and has different patentable weights.

- II. Claims 12-13, 19-20, 31, 35, 37-44, drawn to chimeric monoclonl antibody and a method of making and method of using the chimeric antibody, classified in class 435, subclass 2.
- III. Claims 14-15, 32, 36, 45-52, drawn to a humanized antibody and a method of making and method of using a humanized antibody, classified in class 435, subclass 343.
- IV. Claims 24-28, drawn to a single chain antibody and a method for reducing tumor growth by using a single chain antibody, classified in class 424, subclass 134.1.
- V. Claim 29, 33, drawn to a process for preparing a polypeptide that consists of the variable region of a monoclonal antibody that specifically neutralizes activation of a receptor flt-1, classified in class 435, subclass 69.1.
- VI. Claim 30, 34, drawn to a process for preparing a polypeptide comprising an amino acid sequence consisting of the hypervariable region of a monoclonal antibody that specifically neutralizes activation of a receptor flt-1, classified in class 435, subclass 91.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

Application/Control Number: 10/090,711

Art Unit: 1648

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different agents used for different purpose and produce different biological effects, e.g. the product of Group I is nucleic acid, whereas the product of the group IV is an antibody.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods that use different procedures and produce different biological results, e.g. the method of Group V is for preparing a polypeptide comprising a variable region sequence of a monoclonal antibody, whereas the product of the group VI is for producing a polypeptide with hypervariable region.

Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of group I can be made with cell-to-cell fusion rather then using a polypeptide.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for one of the Groups are not required for another one of the Groups, restriction for examination purposes as indicated is proper.

- 1. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Art Unit: 1648

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

June 16, 2003

Accognin